Epos™ Ultra
Patient Information

Extracorporeal Shockwave Therapy (ESWT)

Dornier Epos™ Ultra

A Treatment Option for Plantar Fasciitis

DornierMedTech

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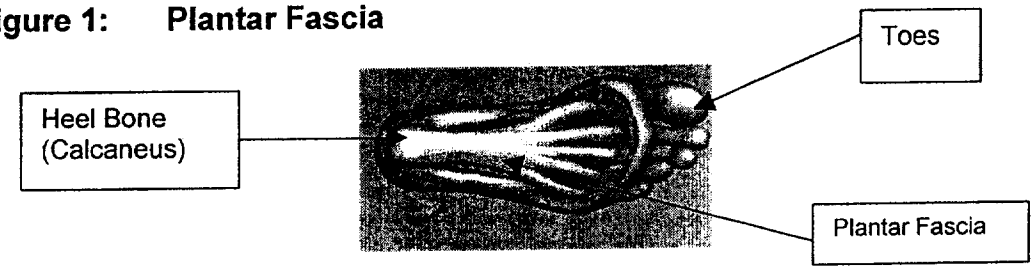
Purpose of the Device

The purpose of the Dornier Epos™ Ultra medical device is to treat chronic plantar fasciitis. Plantar fasciitis is frequently referred to as "heel spurs."

As seen in Figure 1 below, the plantar fascia stretches along the bottom of the foot and is responsible for maintaining the arch of your foot. When the plantar fascia pulls away from the bone, your heel will hurt. Your body reacts by filling in this space with new bone, known as a *"heel spur."* Most people think that heel spurs are the cause of their foot pain. The pain is caused, however, by the inflammation or irritation of your plantar fascia.

Figure 1: Plantar Fascia



Factors that Increase Your Risk for Heel Spurs

- Plantar fasciitis is caused by a number of factors and is a common sports injury among runners, walkers and athletes.
- Overweight people and those whose jobs require a lot of standing or walking are also at higher risk.
- Other factors leading to plantar fasciitis include flat or high-arched feet, worn out or improper shoes, jogging on sand and increasing age.

It is intended that the Epos™ Ultra deliver a complete treatment during a single treatment session. ESWT is recommended for the treatment of chronic plantar fasciitis for patients with symptoms of plantar fasciitis for six months or more and a history of unsuccessful conservative therapy such as that listed in the Alternative Treatments section on page 7.

Description of the Device

The Epos™ Ultra is a therapy device that uses Extracorporeal Shock Wave Therapy (ESWT) to treat chronic plantar fasciitis. This same shock wave technology has been used to treat kidney stones.

The system was designed and manufactured in Germany by Dornier Medizintechnik and uses shock wave therapy to help reduce the pain associated with chronic plantar fasciitis (heel spurs). An important benefit of this therapy is that it is delivered outside the body (extracorporeally), which eliminates the risk of invasively cutting into the body.

Figure 2 gives a pictorial view of the Dornier Epos™ Ultra System.

The therapy head of the Epos™ Ultra uses a magnetic current impulse to generate shock waves. Shock waves are a type of sound wave. A pulse of electrical energy causes strong magnetic fields, which produce forces that vibrate and create a pressure wave or shock wave. The shock waves travel through the water in the shock wave source (coupling cushion) mounted to the therapy head, where they are precisely focused by a lens to the target tissue without any energy loss or damage to the body tissue.

Figure 2: Dornier Epos™ Ultra

1 Ultrasound System
2 Ultrasound Transducer
3 Hand Held Control Unit
4 Therapy Head
5 Isocentric Locating Arm (aligns ultrasound and therapy head)
6 Transportable Cart

When should the Epos™ Ultra Not Be Used (Contraindications)?

There are no known contraindications to extracorporeal shock wave treatment with the Epos™ Ultra for treatment of plantar fasciitis.

Risks/Benefits

What are the risks of having this treatment?

There are few major side effects or risks with shock wave therapy, which may include the following:

- Pain and/or discomfort during treatment
- Pain or swelling for a brief period following treatment
- Localized numbness, tingling, or decreased loss of sensation in the foot or at the site of shock wave delivery; and
- Local blood clotting beneath the skin (subcutaneous Hematoma), minor bruising, or small purplish spots on the skin (petechial bleeding) in the foot or at the treatment site

Other potential adverse events may include:

- Rupture of plantar fascia
- Possible bleeding and/or infection at the injection site related to injection of local anesthetic
- Temporary or permanent nerve damage associated with the injection or with the treatment
- Misdirection of extracorporeal shock wave energy to a major nerve or blood vessel, resulting in injury; and/or
- Anesthesia complication, including allergic reactions to local anesthetic agents

With the injection of a local anesthetic *(xylocaine)* 15-20 minutes prior to treatment, you may experience possible bleeding and/or infection at the injection site.

Speak to your health care provider should you have any questions concerning the risks associated with this therapy. Tell your health care provider if you have any of these side effects after treatment.

What are the benefits of having this treatment?

Extracorporeal shock wave therapy for the treatment of plantar fasciitis is believed to be a safe and effective alternative to the usual treatment methods available. Shock wave therapy has been shown to relieve pain on the basis of 3 month clinical data and provide a short recovery period. This therapy may eliminate the need for surgery.

Expectations of the Device

You will be evaluated before treatment to make sure you are eligible. You must have had plantar fasciitis symptoms for at least six months and have a history of unsuccessful conservative therapy. The actual treatment will take approximately 45 minutes. It is important that you remain alert and provide feedback to the doctor during treatment to ensure that the shock waves are focused directly on the center of your pain. Your feedback will also assist the doctor to properly assess and document any pain you have during treatment. If severe pain is experienced, you should ask the doctor to stop treatment. You may be required by your physician to return for short follow-up visits. Questionnaires (e.g. VAS and Roles & Maudsley) may be used to assess your pain level before and after treatment.

Procedure Associated With the Device

The therapy head *(which houses the shock wave source)* on the Epos™ Ultra machine will then be joined to, or *"coupled"* with, your foot. Figure 3 below provides a pictorial view of the therapy head as it is joined (coupled) to the patient's foot.

- Before therapy begins, you'll be asked to point to the area of your foot with the most pain, which the physician will mark with an "X."
- You will then be given a shot of 5ml of 1% xylocaine to numb the area prior to the beginning of treatment. Based on the level of pain experienced during treatment, you may receive more than one injection of local anesthetic.
- After you have received the injection, you will be asked to lie down on the exam table. A gel will be applied to your foot and the therapy head and treatment will then begin.

Figure 3: Therapy Head Joined (coupled) to Patient's Foot

Using a hand-held control, your doctor will release the shock waves with the push of a button. The position of the shock wave source may be changed during treatment by using the ultrasound image as a guide.

Warnings:

You are encouraged to openly discuss with your physician any reason(s) why you should not undergo shock wave treatment for your heel pain. The Dornier Epos Ultra bas not been used to treat people with the following:

- A pacemaker or who have history of active heart disease
- Less than 18 years of age
- An infection in the area to be treated
- A history of current or recent therapy that compromises tissue healing
- Pregnant
- Problems with circulation or bleeding
- Diabetic neuropathy (nerve damage due to diabetes)
- Diseases or disorders of the nerves
- Diseases or disorders of bone structures
- A heel or ankle fracture
- Significant disease of the blood vessels
- Rheumatoid arthritis (pain, stiffness, swelling of the joints)
- Plantar fascial rupture
- Previous treatment with non-steroidal anti-inflammatory drugs or any other conservative therapies within two weeks of treatment and/or corticosteroid injection within one month of treatment
- Previous surgery for plantar fasciitis
- A history or documented evidence of immune system deficiencies (autoimmune disease)

Alternative Treatments

Plantar fasciitis is a common cause of heel pain. It is the most common diagnosis for pain in the bottom of the heel. Current conservative treatments for plantar fasciitis include:

- Rest
- Physical therapy
- Heel cushions
- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Corticosteroid injections
- Taping
- Orthotics
- Shoe modifications

- Nightsplinting
- Casting

**** Your personal physician is your best source of information and can better explain treatment options in more detail.***

A minimum of six months of conservative therapies should be exhausted prior to considering surgical intervention. If any measure of improvement during this time is noted, another six months of therapy should continue. In some cases, it may take as long as a year for symptoms to resolve.

Clinical Studies

A clinical study was conducted with a total of 150 patients enrolled at six clinical centers. Patients received a single, outpatient extracorporeal shock wave treatment to determine if ESWT can safely and effectively relieve the pain associated with plantar fasciitis. One-half the patients received a real treatment and one-half of the patients received a "placebo" or a "false" treatment, meaning they didn't actually get the treatment, but thought they did.

Before receiving the ESWT, all patients reported their pain for the first few minutes of walking in the morning by placing a mark on a line that had a 0 on the left end, indicating no pain, and a 10 on the right end, indicating severe pain. This evaluation was called the Visual Analog Scale. The average pain score of all patients who received a real treatment decreased from 7.7 before treatment to 3.4 at 3 months after treatment. This was an average improvement of 56.5%. In the placebo group, the mean score decreased from 7.7 at baseline to 4.1 at 3 months post-treatment, a mean percent improvement of 46.6%.

The Roles and Maudsley is an assessment scale that was used to evaluate pain for participants in the clinical trial. This questionnaire asked patients to rate their health according to the following:

1 - Excellent
2 - Good
3 - Fair
4 - Poor

Out of the patients that received the real treatment, 98.7% evaluated their health before treatment with a score of 3 or 4. In the placebo group 98.6% evaluated their pain status with a score of 3 or 4. At 3 months after the treatment, 61.6% of patients that received the real treatment had good to excellent results, compared to only 39.7% of the placebo patients.

Adverse Events

Any problem affecting the health and safety of the patient that was reasonably thought as caused by, or probably caused by, the Dornier Epos™ Ultra, as determined by the physician, was reported.

All but one complication resolved with little or no intervention. One patient in the Active group reported loss of sensation (paresthesia) at the 3-5 day follow-up visit. This adverse effect was reported as unresolved at the 6 week, 3 month and 6 month follow-up visits. The patient discontinued from the study prior to the 12 month follow-up visit.

The most common adverse events were pain during treatment and pain 3-5 days post-treatment. Pain during treatment occurred in 40% of the patients. Pain post-treatment through 3 months follow-up was reported in 34.7% of patients. The table below lists the adverse events that occurred during the clinical study.

Adverse Events Treatment Through 3 month Follow Up

Adverse Event	Active Treatment Patients (Number = 76)			Sham Treatment Patients (Number = 74)		
	Number of Patients[1]	Number of Occurrences	Percent of Patients	Number of Patients[1]	Number of Occurrences	Percent of Patients
Pain During Treatment[2]	55	55	73%	5	5	7%
Pain Post Treatment[3]	28	31	37%	24	26	32%
Swelling (Edema)	5	5	7%	6	7	8%
Bruising (Ecchymosis)	5	5	7%	4	4	5%
Small purplish spots on the skin (Petechiae)	0	0	0%	1	1	1%
Rash	1	1	1%	0	0	9%
Partial loss of sensation (Hypesthesia)	2	3	3%	6	6	8%
Nerve Irritation (Neuralgia)	1	1	1%	0	0	0%
Abnormal skin sensation, e.g. burning, tingling, etc. (Paresthesia)	3	3	4%	3	4	4%
Total Events	104			53		

1. Number of patients experiencing at least one occurrence
2. Pain during shock wave application: statistical significance with p-value <0.0001 by Fischer's Exact Test

3. Pain experienced immediately after treatment through 3 month follow-up

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